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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Matts Andersson

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EXAMINER

KESSLER, CHRISTOPHER S

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/500,211	Applicant(s) ANDERSSON ET AL.	
	Examiner CHRISTOPHER KESSLER	Art Unit 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/12/08; 6/28/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of claims 6-13 in the reply filed on 19 June 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 19 June 2008.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 13 is rejected under 35 U.S.C. 101 because the claimed invention does not meet the statutory limitations of a process. Although a claim should be interpreted in light of the specification disclosure, it is generally considered improper to read limitations contained in the specification into the claims. See *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969) and *In re Winkhaus*, 527 F.2d 637, 188 USPQ 129

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(CCPA 1975), which discuss the premise that one cannot rely on the specification to impart limitations to the claim that are not recited in the claim.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites "Use in the production of a device made of compressible bone-compatible and/or tissue-compatible powder material, for example titanium powder, and provided with a bone-growth-stimulating agent, preferably HA, characterized in that an impact-type compaction machine with a high impact compaction energy is used to compress the powder material and said agent in powder form to give a composite material." It is unclear from the instant claim as to what is being used and how.

7. Claim 13 can not be further examined on the merits, as it is unclear what is being claimed.

8. Claims 6-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "the human body." There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "the bone-compatible and/or tissue-compatible powder material." There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "the impacting unit." There is insufficient antecedent basis for this limitation in the claim.

Claim 8 recites the limitation "the fraction." There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "the powders." There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "the dry state." There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "the titanium particles." There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "the HA particles." There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the positions." There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the HA particles." There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the composite material." There is insufficient antecedent basis for this limitation in the claim.

9. The term "high impact compaction energy" in claim 6 is a relative term which renders the claim indefinite. The term "high impact compaction energy" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no indication in the instant specification as what range of energy is meant by "high impact compaction energy." Each of claims 7-12 is dependent on claim 6 and is therefore also rejected as being indefinite.

The term "considerable purity" in claim 8 is a relative term which renders the claim indefinite. The term "considerable purity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no indication in the instant specification as what range of purity meets the limitation of being "considerable."

The term "relatively small particle size" in claim 8 is a relative term which renders the claim indefinite. The term "relatively small particle size" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no indication in the instant specification as to what range of particle size is meant by "relatively small."

The term "substantial density" in claim 11 is a relative term which renders the claim indefinite. The term "substantial density" is not defined by the claim, the

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specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no indication in the instant specification as to what range of density is meant by "substantial density."

The term "substantial surrounding" in claim 11 is a relative term which renders the claim indefinite. The term "substantial surrounding" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no indication in the instant specification as to what extent of surrounding is meant by "substantial surrounding."

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 6, 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over R. Rogier and F. Pernot, "Phosphate glass-ceramic-titanium composite materials," *Journal of Materials Science* **26** (1991) 5664-5670 (hereinafter "Rogier"), in view of WO 00/30788 (hereinafter "Troive").

Regarding claim 6, Rogier teaches the invention substantially as claimed. Rogier teaches a method of making a composite material for use in a prosthetic implant (see 1.Introduction). Rogier teaches that the method is used to produce a seal for the implant that will act as an intermediate layer between the core of the implant and a bioactive coating (see 1.Introduction), meeting the limitation of at least one surface or one portion, is arranged to be applied to bone and/or tissue in the human body, for example jaw bone, and which, at the surface or portion, is provided with an agent which stimulates bone growth. Rogier teaches wherein powders of a bone-compatible material (titanium) and an agent which stimulates bone growth (CAP) are mixed in powder form and compacted to form a composite (see 2.1 Base products and preparation of composites).

Rogier does not teach applying the mixture in a mold cavity belonging to a mold applied in a machine which effects impact compaction and which operates with a high impact compaction energy, activating the impacting unit of the machine so that it acts on the mold and transfers the energy to the powder mixture and thereby creates a blank for the device, and treating the blank in one or more treatment units for producing the device from the blank.

Troive teaches a method of consolidating powders (see Abstract, Fig. 2, DETAILED DESCRIPTION). Troive teaches that a powder is placed into a mold cavity in a mold applied in a machine which operates with a high impact compaction energy (see Abstract, Fig. 2, DETAILED DESCRIPTION). Troive teaches that the machine is

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activated and transfers energy to the powder to cause its compaction (see Abstract, Fig. 2, DETAILED DESCRIPTION).

Rogier and Troive do not teach wherein the blank is treated in one or more treatment units for producing the device from the blank. However, further processing steps would have been obvious to one of ordinary skill in the art at time of invention. For example, the seal material thus formed would be machined or cut to size for the prosthetic implant desired. The examiner takes Official Notice that it would have been obvious to have cut or machined the material to size in order to use it in a prosthetic implant. Applicant is further directed to MPEP 2144.03.

It would have been obvious to one of ordinary skill in the art at time of invention to have altered the method of Rogier by using the method of compaction and machine of Troive, because Troive teaches that the method is a fast and effective way of compacting powder (see pp. 5-6).

Regarding claim 7, The examiner takes Official Notice that it would have been obvious to have cut or machined the material to size in order to use it in a prosthetic implant. Applicant is further directed to MPEP 2144.03.

Regarding claim 10, Troive teaches wherein the machine is controlled so as to generate greater than 335 Nm of impact compaction energy (see p. 11).

12. Claims 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over A Bishop, et al., "A functionally gradient material produced by a powder metallurgical

process,” *Journal of Materials Science Letters* **13** (2003) 1516-1518 (hereinafter “Bishop”), in view of WO 00/30788 (hereinafter “Troive”).

Regarding claim 6, Bishop teaches the invention substantially as claimed. Bishop teaches a method of making a composite material comprising hydroxyapatite in a titanium metal matrix (see p. 1516). Bishop teaches wherein the hydroxyapatite material is present to stimulate bone growth, and wherein the material is to be used for an implant prosthesis (see p. 1516), meeting the limitation of wherein at least one surface or one portion, is arranged to be applied to bone and/or tissue in the human body, for example jaw bone, and which, at the surface or portion, is provided with an agent which stimulates bone growth. Bishop teaches wherein the titanium powder and hydroxyapatite powder are mixed together and applied to a mold cavity belonging to a mold (see p. 1516).

Bishop does not teach applying the mixture in a mold cavity belonging to a mold applied in a machine which effects impact compaction and which operates with a high impact compaction energy, activating the impacting unit of the machine so that it acts on the mold and transfers the energy to the powder mixture and thereby creates a blank for the device, and treating the blank in one or more treatment units for producing the device from the blank.

Troive teaches a method of consolidating powders (see Abstract, Fig. 2, DETAILED DESCRIPTION). Troive teaches that a powder is placed into a mold cavity in a mold applied in a machine which operates with a high impact compaction energy (see Abstract, Fig. 2, DETAILED DESCRIPTION). Troive teaches that the machine is

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activated and transfers energy to the powder to cause its compaction (see Abstract, Fig. 2, DETAILED DESCRIPTION).

Bishop and Troive do not teach wherein the blank is treated in one or more treatment units for producing the device from the blank. However, further processing steps would have been obvious to one of ordinary skill in the art at time of invention. For example, the seal material thus formed would be machined or cut to size for the prosthetic implant desired. The examiner takes Official Notice that it would have been obvious to have cut or machined the material to size in order to use it in a prosthetic implant. Applicant is further directed to MPEP 2144.03.

It would have been obvious to one of ordinary skill in the art at time of invention to have altered the method of Bishop by using the method of compaction and machine of Troive, because Troive teaches that the method is a fast and effective way of compacting powder (see pp. 5-6).

Regarding claim 7, The examiner takes Official Notice that it would have been obvious to have cut or machined the material to size in order to use it in a prosthetic implant. Applicant is further directed to MPEP 2144.03.

Regarding claim 8, Bishop teaches that titanium powder and hydroxyapatite powder are used, and that the titanium has a relatively small particle size (see p. 1516). Bishop further teaches that the HA particles have a particle size within the range of 72-118 μm (see p. 1516), said range overlapping the range as claimed and establishing a prima facie case of obviousness for that range. It would have been obvious to one of ordinary skill in the art at time of invention to have used particles within the range as

claimed, because Bishop teaches the same utility over an overlapping range. Applicant is further directed to MPEP 2144.05.

Regarding the limitation of "considerable purity," Bishop teaches that the powder is titanium powder, meeting the limitation of the claim. The examiner notes that the percentage of purity of the titanium is not mentioned in Bishop. However, the purification of the titanium or the selection of a more pure form of titanium would have been obvious to one of ordinary skill in the art at time of invention. Applicant is further directed to MPEP 2144.04 VI.

Regarding claim 9, Bishop teaches that in the mixing step, the mixture consists of 90% titanium powder and 10% hydroxyapatite powder (see p. 1516), meeting the limitation of "ca. 95% titanium powder and 5% HA powder." Bishop teaches that the powders are mixed together dry in a rotating mixer (see p. 1516), meeting the limitation of mixed in the dry state with agitation and stirring.

Regarding claim 10, Troive teaches wherein the machine is controlled so as to generate greater than 335 Nm of impact compaction energy (see p. 11).

Regarding claim 11, Bishop teaches that the particles are compressed to a substantial density, and that there is substantial surrounding of the HA particles (see pp. 1516-1517).

Regarding claim 12, Bishop teaches that the positions of the HA particles are controlled upon mixture and application in the mold cavity of the mold (see pp. 1516-1517). Bishop does not teach that the blank is machined so that HA particles are present at the surface exposed to the bone and/or tissue. The examiner takes Official

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Notice that it would have been obvious to have cut or machined the material to size in order to use it in a prosthetic implant. Applicant is further directed to MPEP 2144.03.

The machining thus taking place would have exposed HA particles to the surface exposed to the bone and/or tissue in order to allow bone ingrowth (see p. 1516).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Zhang et al. "Toughening of calcium hydroxyapatite with silver particles," *JOURNAL OF MATERIALS SCIENCE* **32** (1997) 235-243 teaches to reinforce a sintered HA matrix with silver. Chu et al., "Hydroxyapatite-Ti functionally graded biomaterial fabricated by powder metallurgy" *Materials Science and Engineering A* **271** (1999) 95-100 teaches to make a functionally graded Ti-HA composite material. Chu et al., "Fabrication and characterization of hydroxyapatite reinforced with 20 vol % Ti particles for use as hard tissue replacement," *Journal of Materials Science: Materials in Medicine* **13** (2002) 985-992 teaches to form a composite of Ti and HA. 4,722,870 and 5,711,763 each teach to use a titanium-HA composite material for an implant device.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER KESSLER whose telephone number is (571)272-6510. The examiner can normally be reached on Mon-Fri, 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Roy King/
Supervisory Patent Examiner, Art
Unit 1793

csk